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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/696,717	10/29/2003	Wylie Vale	D6257D	6470

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David L. Parker
Fulbright & Jaworski LLP
600 Congress Avenue
Suite 78701
Austin, TX 78701

EXAMINER	
STOICA, ELLY GERALD	
ART UNIT	PAPER NUMBER
1647	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	12/19/2006	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/696,717	VALE ET AL.	
	Examiner	Art Unit	
	Elly-Gerald Stoica	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 October 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *34-40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *34-40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *05/27/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restriction

1. Applicant's election without traverse of claims related to Group I claims, directed to the augmentation of activin signaling is acknowledged.

Status of the claims

2. The original set of claims (1, 4-12, and 15-33) were canceled by the Applicant and new claims 34-40 are pending.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claim 38 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treatment for reproductive disorders, does not reasonably provide enablement for developmental, skin, bone, hepatic, hematopoietic or central nervous systems disorders. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The factors considered when determining if the disclosure satisfies the enablement requirement and whether any necessary experimentation is "undue" include, but are not limited to:

1) nature of the invention, 2) state of the prior art, 3) relative skill of those in the art, 4) level of predictability in the art, 5) existence of working examples, 6) breadth of claims, 7) amount of direction or guidance by the inventor, and 8) quantity of experimentation needed to make or use the invention. In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

The claim is drawn a method of inhibition of inhibin/betaglycan complexes on with an anti-betaglycan antibody (thus augmenting the activin-induced signaling) used in the treatment of reproductive, developmental, skin, bone, hepatic, hematopoietic or central nervous system disorders. In the art, the role of the activin-inhibin interplay in reproductive, skin and fibrotic disorder was well established (e.g., Ferguson et al., GB2306481A, 05/07/1997; Woodruff TK, Biochem. Pharmacol, 55, 953-963, 1998). Inhibin was also known to function as a tumor suppressor gene in hepatic cells (Lee et al, US Pat. No. 5929213, 08/27/1999). Localization of activin receptors in neuronal cells, as well as activin signaling in mesenchymal signaling in tooth development were also known (Shoji et al., Biochem. Biophys. Res. Commun., 246,320-324, 1998; Ferguson et al., Genes & Dev., 12, 2636-2649, 1998). The relationship between Inhibin, activin and betaglycan was further uncovered by Lewis et al. (Nature, 404, 411-414, 2000). However, based on just the presence of these three players at a certain time at the surface of the cells, one could not have predicted, without experimentation, what the effect of blocking inhibin/betaglycan interaction would have been. The amount of guidance and the working examples offer enablement for reproductive disorder linked to the FSH production. The mere determination of the presence of betaglycan in the

normal adult brain for instance, as presented in the application, is considered, even by the Applicant, a possibility and not a certainty of interaction with inhibin (example 7 in the instant application). Therefore, without undue experimentation, the breadth of the claim has to be limited to reproductive disorders.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 37 is rejected under 35 U.S.C. 112, second paragraph, for failing to further limit the claim 36. The method recited in claim 37 does not add any new step to the invention of claim 36, since it was known in the prior art (US Pat. 4973577, col. 11, lines 1-11) that the inevitable outcome of performing the method of claim 36 would be an increase in FSH production.

Double Patenting

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to

be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claims 34-40 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4 of U.S. Patent No. 6692744 ("744" patent). Although the conflicting claims are not identical, they are not patentably distinct from each other because they address the same subject matter. For instance, claim 34 and 35 of the instant application read "A method of inhibiting the formation of inhibin/betaglycan complexes on the surface of a cell by contacting the cell with an anti-betaglycan antibody" and "The method of claim 34, wherein activin-induced signaling in the cell is increased".

Claim 1 of the "744" patent reads "A method of augmenting activin-induced signaling in a cell comprising the step of: inhibiting the formation of inhibin/betaglycan complexes on the surface of said cell by an anti-betaglycan antiserum directed against an extracellular epitope of betaglycan". The inhibition of inhibin/betaglycan complexes on the surface of a cell by contacting the cell with an anti-betaglycan antibody would necessarily bring the augmentation of activin induced signaling. The anti-betaglycan antibody has to be directed against the extracellular domain of betaglycan to physically block the interaction of betaglycan/inhibin.

Claim 35 refers to the method of claim 35, wherein the cell is a pituitary cell. Claim 2 of the "744" patent reads "The method of claim 1, wherein said cell is a pituitary cell".

Claim 37: "The method of claim 36, wherein the pituitary cell increases production of follicle stimulating hormone (FSH)", is almost identical with claim 3 of the "744" patent: "The method of claim 2 wherein augmentation of activin signaling increases the production of Follicle Stimulating Hormone (FSH) by said cell."

Claim 4 of the "744" patent reads: "The method of claim 3, wherein said method enhances fertility". Claims 38 is drawn to the method of claim 34, wherein the method is used to treat reproductive, developmental, skin, bone, hepatic, hematopoietic or central nervous system disorders. Claim 39 limits the treatment to a reproductive disorder while claim40 further limits it to reduced fertility. Since the method of claim 4 of the "744" patent enhances fertility it necessarily means that it treats reduced fertility which is a reproductive disorder part of the recitation of claim 38.

Conclusion

8. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elly-Gerald Stoica whose telephone number is (571) 272-9941. The examiner can normally be reached on 8:30-17:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda G. Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Lorraine Spector

LORRAINE SPECTOR
PRIMARY EXAMINER